

Chapter II

Review of Literature



There is only one work which concerns on costs of Thai FDA and there are few works in case of regulatory agencies or cost of regulation.

One relevant work was done by Tangcharoensatien V. et.al. (1993, unpublished) in examining unit cost of pre-marketing activities of Thai FDA. Pre-marketing activities of each division were investigated, using time consumed as a criteria to adjust the amount of outputs and then convert them to money used in each activity. Some criterias such as the number of staff, the difficulties of work, capital cost of public relationship and public education, etc were used for resource allocation from related units to the observed units. The results indicated that activity on manufacturing licence approval was one of the most expensive activities in each division. For drug control, registration of new formularies consumed the highest cost (41,191 Baht/unit, 1993). This study was the starting point for the administrators to look at the efficiency and performance of Thai FDA.

The other work related to the cost of food safety regulation, was done by John M. Antle (1998). By using an accounting methodology, the U.S. Department of Agriculture's estimates of the costs of new food safety regulations in the meat industry indicated that the benefits will exceed the costs of the regulations by hundreds of millions or billions of dollars annually. The purpose of the study was to develop an econometric approach to the estimation of the plant-level costs of quality regulations, such as food safety regulations. The theoretical and empirical models

proposed in the study were based on the integration of Rosen's (1974) model of a competitive industry producing quality-differentiated products with Gertler and Waldman's (1992) model of a quality-adjusted cost function. Using plant-level data available from the Census of Manufacturers, quality-adjusted cost functions were estimated for beef, pork and poultry slaughter and processing plants. These cost functions were used to assess the potential costs of the food safety regulations imposed on the industry. Statistical tests strongly reject the assumption that variable cost of production is independent of product safety, showing that food safety regulations affect the overall operating efficiency of meat slaughter and processing plants. The econometric models estimated in this study indicated that the plant-level costs of the regulations, assuming they are 20 percent effective, were likely to be in the range of \$535 million to \$4.8 billion (1995 dollars). Thus, the findings of the study casted doubt on the proposition that there was a virtual free lunch in food safety regulation in the meat industry, and showed that the costs of these regulations could well exceed estimated benefits.

J. Luis Guasch and Robert W. Hahn (1999) investigated that there are five general approaches to estimating the cost of regulation.

1) *Econometric studies* typically evaluate output markets directly or use production and cost functions to measure the impact of regulations. Eventhough such studies provide a formal statistical apparatus with which to test hypotheses, their formulation is quite general, lustering over the exact nature of production functions. Macroeconomic models are sometimes used in accordance with econometric estimation to assess the economywide effects.

- 2) *Expenditure evaluation studies* frequently rely on surveys of firms or businesses to determine costs of compliance. Direct surveys make easily quantified and large estimates of the cost of regulation, but such surveys face many problems. The first involves potential respondent biases. For example, a firm may inflate its estimated costs in hopes that politicians will consider providing regulatory relief. More important, direct expenditure studies do not specify a counterfactual. For instance, a pharmaceutical company may choose to install hazardous deterrent equipment even without a regulation forcing it to do so. Attributing the added cost of such equipment to government regulation overstates the impact of regulation.
- 3) *Engineering approaches* calculate the added cost of installing equipment directly, adjusting for quality changes.
- 4) *Productivity studies* draw the difference between observed productivity changes over time and those that would have occurred in the absence of one or more regulations. These studies face several problems, such as their reliance on expenditure data and an inability to specify the determinants of macroeconomic performance over time.
- 5) *General equilibrium models* which have become more popular recently, examine how a perfectly competitive market responds to a new policy. The effects of a regulation can be linked to changes in output, employment, and in some cases welfare. Although this approach is not without problems, including substantial data requirements, its results provide a better picture of regulatory effects in some

cases. Some methodological issues decline to defining the conditions under which it is reasonable to assume away all but the most meaningful effects.

In the same paper, they also examined the previous studies on costs and benefits of regulation. They found that Hahn and Hird (1991) distinguished between transfer costs and efficiency costs. Transfers exhibit payments from one group to another (for example, producers to consumers); efficiency costs represent net losses in producer and consumer surpluses. Both measures are important, but for different reasons. Transfer payments provide a measure of the winners and losers from regulatory change, while changes in net surplus provide an indication of the whole impact of a regulation on the economy or industry under investigation. Some studies, which show estimates of the costs of regulation in the United States, demonstrate that the efficiency costs appear to be much smaller than the transfer costs. Data from the Executive Office of the President (1990) showed the administrative cost of consumer product safety is more than 0.034 billion of dollars. The studies of Crandall (1988), Denison (1979), and Viscusi (1983) demonstrated the costs of occupational safety and health are in between 8.5-9.0 billion of dollars and the study of Peltzman (1973) showed the cost of drugs regulation is less than 1.5 to 3.0 billion of dollars. They also found some few studies outside the United States. In Australia the total cost of regulation was estimated to be 9-19 percent of GDP in 1986 (OECD 1996) and Mihlar (1996) estimates that the costs of regulation in Canada amounted to 12 percent of GDP.